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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,742	11/30/2001	Davin C. Dillon	210121.491C7	3670

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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,742	DILLON ET AL.	
	Examiner	Art Unit	
	Teresa E Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2005 and 23 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 23, 2004 has been entered.

2. The declaration of Dr. David Dillion, submitted on November 23, 2004 has been considered but did not overcome the rejection of claims 1, 3 and 4 under 35 U.S.C. 101, utility, for reasons given in the "Response to Arguments" below.

3. The petition under 37 C.F.R. 1.48(b) to amend inventorship, filed November 23, 2004, has been approved.

Response to Arguments

4. In the response filed November 23, 2004, Applicants argue that the sequence of SEQ ID NO: 52 was found to be overexpressed two-fold as compared to normal tissue, and, therefore, SEQ ID NO: 305, which comprises SEQ ID NO: 52, could be used for diagnostic purposes. In addition, Applicants argue that the declaration of Dr. Dillion provides evidence of overexpression of SEQ ID NO: 305 in breast tumor tissues but not in a panel of normal tissues, therefore, the sequence would have utility as a diagnostic tool for breast cancer.

However, these arguments are not considered persuasive. First, a mere fact that a polynucleotide is overexpressed in certain tissue is not an indication of the polynucleotide being of diagnostic value, if it had not been shown that a correlation between the overexpression and disease, in this case, breast cancer, is statistically significant. Such evidence is missing in the declaration of

Dr. Davin Dillion. On page 4 of the declaration, in Table 1, the results of immunohistochemical analysis of normal and breast tissue indicate that the protein expressed from SEQ ID NO: 305 is present in all of normal and 90% of the breast tumor cells, but these results actually contradict the notion that the presence of the protein expressed from SEQ ID NO: 305 could be used for diagnostic purposes. Further, these results are not relevant to the issue of overexpression of SEQ ID NO: 305 in normal vs. breast tumor tissues.

The data from real-time PCR analysis of overexpression of SEQ ID NO: 305, presented in Figure 2, are not persuasive, either. From the panel of 25 tumor breast tissues, only 8 tissues showed overexpression of SEQ ID NO: 305, which means that the overexpression of polynucleotide with SEQ ID NO: 305 is not diagnostic of breast cancer, since only 30% of the cancer tissue shows such overexpression. Therefore, there is no proven statistically significant correlation between the overexpression of polynucleotide with SEQ ID NO: 305 and breast cancer, therefore, this polynucleotide does not have a specific and substantial utility.

The rejection of claims 1, 3 and 4 under 35 U.S.C. 101 is maintained.

Claim Rejections - 35 USC § 101, utility

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

6. Claims 1, 3 and 4 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

Polynucleotide with SEQ ID NO: 305 is the cDNA sequence of the open reading frame of a splice variant of B854P referred to as 228686_8 (page 16, lines 3,4). On page 104, Applicants explain that the 228686_8 sequence was recovered from LifeSeq Gold™ database by comparing the database with a polynucleotide with SEQ ID NO: 52 (B854P), which may represent a potential splice form of the B854P gene. The 228686_8 sequence encodes a putative protein with SEQ ID NO: 307, the cDNA of which has SEQ ID NO: 305. Applicants assert that the nucleic acid sequence denoted as 228686_8 is full-length and is 51% identical to rabbit P450 cytochrome

sequences (page 104, lines 8-22). Applicants did not provide the sequence alignment or an indication to which cytochrome P450 the sequence was compared.

Sequence search performed at USPTO did not reveal any significant homology to P450 proteins of any origin. The following homologies were found (see copies of sequence alignments):

1) 99.9% identity to a polynucleotide with SEQ ID NO: 29 from a patent publication No. US 2003/0027988 A1. This polynucleotide is overexpressed in colon cancer cells, but no structural or functional information for the protein encoded by it was provided, and no specific or substantial utility was described for either the polynucleotide or the protein encoded by it.

2) 99.9% identity to SEQ ID NO: 55 of the patent publication No. US 2003/0022334 A1. Again, this publication does not contain any information about the function of a protein encoded by SEQ ID NO: 55, and does not provide any specific or substantial utility was described for either the polynucleotide or the protein encoded by it.

3) 21.2% identity to a nucleic acid sequence with an accession number AI820775, which is human EST fragment, similar to rabbit cytochrome P450 4B1 (according to clone definition); no functional information provided.

4) 20.4% identity to a nucleic acid sequence with an accession number BI772715, which is human EST fragment; no function information provided.

Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. However, in all of the four cases above none of the similar polynucleotides has utility in view of the fact that the first two encode proteins with unknown function and undetermined utility, and the third and fourth ones are short polynucleotide fragments with unknown function.

The claimed polynucleotide (SEQ ID NO: 305) is not supported by a specific asserted utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to a wide variety of polynucleotides. The specification states that the polynucleotides may be useful as hybridization probes, PCR primers (page 33, lines 9-22; page 39, lines 8-29; page 40; page 41, lines 1-18), for encoding of polypeptides cross-reactive with other polypeptides (page 33, lines 23-29), for sequence comparisons with other polynucleotides (page 34, lines 12-29; page 35), for mutagenesis to provide derivative polypeptides (page 36, lines 23-29; page 37, 38), for therapeutic purposes as antisense ologonucleotides (page 41, lines 19-29; page 42; page 43, lines 1-7), for design of ribozymes (page 43, lines 8-29; page 44, 45; page 46, lines 1-20), parts of expression vectors and for gene therapy and vaccines (page 72 lines 3-29; page 73). These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed.

Further, the claimed polynucleotide compound is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compound such that another non-asserted utility would be well established for the compounds.

Applicants state in lines 9 and 10 of page 16 that the compositions described in the specification could be used for the therapy and diagnosis of cancer, particularly breast cancer.

However, in order for a polynucleotide (or a polypeptide) to be useful for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide (or a polypeptide) and a disease or disorder. The presence of a polynucleotide (or a polypeptide) in tissue that is derived from cancer cells (in this case from breast cancer cells) is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide (or a polypeptide) to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide (or a polypeptide) is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide (or a polypeptide) as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

7. Claims 1, 3 and 4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teresa E Strzelecka
Teresa Strzelecka
Examiner

1/26/05